REMARKS/ARGUMENTS

Claims 1-4 are pending in the application. Claim 1 has been amended to more clearly recite applicant's claimed composition. The claim amendments are entirely supported by the application as originally filed (see, e.g., p. 2, lines 11-12 of the specification) and thus there is no issue of new matter. Entry of the amendment to claim 1 is respectfully requested. Upon such entry claims 1-4, as amended, will appear in the application for the Examiner's consideration.

Claim Rejection Under 35 U.S.C. §112

The rejection of claim 1 under 35 U.S.C. §112, second paragraph, pertaining to the term "gelling agents" is maintained according to pp. 2-3 of the Office Action.

In response, applicants have amended the subject claim to delete the term "gelling agent". The claim as amended now recites that hydroxyethylcellulose is the only material used for converting the composition into a gel and to render it bioadhesive. No new matter is added by the subject amendment since the claim now merely recites the function of the hydroxyethylcellulose material (which is one of the "gelling agents" taught for use in the present application) to avoid the use of the objected-to term, "gelling agent".

Further to the discussion above with regard to the term, "gelling agent", provided herewith for the Examiner's information are portions from two references, i.e,. Remington's Pharmaceutical Sciences, 17th ed. (1985), A.R. Gennaro (ed.), pp. 290-293 and Di Shayne Cox Gad, Pharmaceutical Manufacturing Handbook: Production and Processes, Vol. 10, pp. 288 and 291 (Google Library) which serve to clarify that a gelling agent is a water-soluble excipient able to enormously increase the viscosity of a medium by swelling within the medium and forming a semisolid preparation known as a gel.

The Examiner is respectfully requested to consider the subject references and to make them of record in the present application. For this purpose they are listed on a form appended at the end of this response. No fee is believed to be due with applicant's submission since the present response is being filed together with a Request for Continued Examination. However, if any fee is due the Office is hereby authorized to charge the required amount to Deposit Account No. 15-0700.

Applicant submits that it is well known among those having an ordinary level of skill in the art that hydroxyethylcellulose (HEC) is a well-known gelling agent used in the preparation of gels to be applied to the skin. However, it is also known that HEC has mucoadhesive properties which, together with the unexpected effect attributable to Transcutol (see, e.g, the Examples provided by the applicant in the present specification), permits the use of the claimed formulation as a mucoadhesive vaginal composition.

The amendment to claim 1 is believed sufficient to overcome the §112 rejection and the Examiner is, therefore, respectfully requested to reconsider and withdraw the subject rejection.

Claim Rejection Under 35 U.S.C. §102

On p. 3 of the Office Action the Examiner maintains the rejection from the previous Office Action of claims 1, 3 and 4 over Arkin et al. (US 2003/0039704) under 35 U.S.C. §102(b). The rejection is respectfully traversed.

In response to the rejection based on the Arkin et al. reference applicant has amended claim 1 such that the claim is now directed to a mucoadhesive vaginal composition in the form of an aqueous bioadhesive gel adapted for the delivery of at least one of active ingredients and principles, the composition comprising hydroxyethylcellulose as the only material used for converting the composition into a gel and to render it bioadhesive, as well as glycerol and diethylene glycol monoethyl ether and at least one surfactant, preservative and acidifier.

The Arkin et al. reference is directed to pharmaceutical preparations adopted for topical administration, that are effective for treating rosacea. As is well known to those of at least ordinary skill in the relevant art, rosacea is a specific pathology affecting the skin, and not the mucosa. The Arkin reference thus does not teach, or even suggest any bioadhesive/mucoadhesive formulations in that, as pointed above, the condition which the compositions disclosed in the subject reference are designed to treat are conditions of the skin (i.e., rosacea) and not the mucosa.

Thus, since the subject reference does not teach or otherwise disclose each and every feature of applicant's formulation as recited in, e.g., claim 1, applicant respectfully submits that claims 1, 3 and 4 are not anticipated by Arkin et al. The Examiner is, therefore, respectfully

requested to reconsider and withdraw the rejection of applicant's claims under 35 U.S.C. §102(b).

Claim Rejections Under 35 U.S.C. §103

On p. 4 of the Office Action the rejection of claims 1-4 under 35 U.S.C. §103 over the Arkin et al. reference is maintained. This rejection is also respectfully traversed.

As indicated above claim 1 has been amended to further distinguish the composition recited therein from the prior art, and particularly the published Arkin et al. application. As now amended the claim is directed to a mucoadhesive vaginal composition. As pointed out further above, i.e., in the discussion of the rejection under 35 U.S.C. §102(b), Arkin et al. is directed to a formulation adapted for treating rosacea which is, thus, topically applied upon the surface of the skin. In contrast, the present invention is directed to mucoadhesive vaginal compositions which - of course, are neither intended nor adapted for administration to the skin surface.

Further to the above, enclosed with this response are several references demonstrating that terms such as "bioadhesive" and "mucoadhesive" are well recognized in the art. These references are also listed on the form appended to the present Response and the Examiner is requested to consider them and make them of record in the present application. It is appreciated by those working in the field of pharmaceutical formulation that the field of bioadhesive/mucoadhesive formulations is entirely separate and apart from that of conventional topical compositions. That is, a reference directed to a topical composition (e.g., Arkin et al.) clearly provides no suggestion to use the formulation(s) described therein in a "mucoadhesive vaginal" application as presently claimed.

For the reasons presented above, the Examiner is respectfully requested to also reconsider and withdraw the rejection under 35 U.S.C. §103 of applicant's claims 1-4.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON March 16, 2010.

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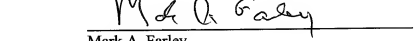
Respectfully submitted,



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